

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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TO

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

08/900,559 07/25/97 CHENG

S 226/242

022249
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LOS ANGELES CA 90071-2066

HM12/0913

EXAMINER

HINES, J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1645

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DATE MAILED:

09/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | |
|-------------------------------|------------------------------|
| Application No. 08/900,559 | Applicant(s) Cheng et al. |
| Examiner Ja-Na Hines | Group Art Unit 1645 |



Responsive to communication(s) filed on Jul 21, 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 10-20 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

Claim(s) _____ is/are allowed.

Claim(s) 10-20 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1641

DETAILED ACTION

Continued Prosecution Application

1. The request filed on July 21, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/900,559 is acceptable and a CPA has been established. An action on the CPA follows.

Response to Arguments

2. Applicant's arguments filed November 15, 1999 have been fully considered but they are not persuasive.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 10-11, 13-15 and 17-20 is rejected under 35 U.S.C. 102(b) as being anticipated by Imrich et al.(US Patent 5,415,994) is maintained.

Applicant argues that Imrich et al., fails to teach a separate sample chamber not in flow communication with the test strip. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the claims of the instant application do not recite any structural limitations with

Art Unit: 1641

respect to the placement of the sample chamber) are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Applicant further argues that Imrich et al., teaches additional limitations, however these aspects of Imrich et al., are not excluded from the claims. The term "comprising" is read as open language and can therefore include any additional features taught by Imrich et al.

Applicant also argues that Imrich et al., does not teach inserting the sampling into the receiving region without further manipulation, however Imrich et al., teaches the extraction chamber allows for pretreatment of a sample generally presented on a swab (col. 3 lines 60-66). The extraction solution may be added to the chamber, and may be treated with an acidic extraction solution such as nitrous acid to expose Group A streptococcus specific antigen (col. 4 lines 15-20). The extraction solution may contain nitrous acid which is relatively unstable, as a result, to generate nitrous acid, sodium nitrite and acetic acid must be mixed immediately before initiation of the antigen extraction process (col. 8 lines 50-63). The sample receiving zone may contain a neutralizing agent which will neutralize the extraction solution and may be placed on the surface of the sample receiving zone (col. 5 lines 1-7). Therefore the sample is presented in the chamber and there is no additional manipulation.

4. Applicant again refers to the Declaration of Richard H. Schwartz under 37 CFR 1.132 filed May 10, 1999. However the Declaration is still insufficient to overcome the rejection of

Art Unit: 1641

claims 10-20 based upon Imrich et al., alone or in combination with Bogart et al., because it refers to OSOM™ system and not to the individual claims of the instant application. The declaration makes references to the OSOM™'s type of housing and its overall sensitivity, however those features are not relevant to the claims of the instant application. There is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MEP. § 716. Therefore, again, the Schwartz Declaration is not persuasive.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imrich et al., in view of Bogart et al., as maintained. Imrich et al., has been discussed above. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious to one of ordinary skill in the art to optimize the experimental parameters and reagents of the method of Imrich et al., by selecting such conventional components for generating nitrous acid and times of

Art Unit: 1641

extraction as taught by Bogart et al., where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill. No more than routine skill is involved in adjusting the amount or concentration of a claimed component in a process to suit a particular starting material in order to achieve the results taught in the prior art.

Applicant also argues about the spatial separation of the assay chamber. In response to applicant's argument that the references fail to show these features of applicant's invention, it is noted that the features upon which applicant relies i.e., the spatial relationship of the assay chamber are not recited in the rejected claims, nor do the claims recite any type of spatially relationship or placement of the assay chamber. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

6. This is a continuation of applicant's earlier Application No. 08/900,559. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1641

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines *jt*
August 24, 2000

Jennifer Graser 9/11/00
JENNIFER GRASER
PATENT EXAMINER